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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,321	03/08/2004	Dennis S. Rushforth	P02655US0	4283
26271	7590	03/09/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,321

Applicant(s)

RUSHFORTH, DENNIS S.

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/8/04</u> | 6) <input type="checkbox"/> Other: ____ |

CLAIMS 1-20 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed March 8, 2004 has been received and entered into the application. As reflected by the attached, completed copy of Form PTO/SB/08A, (1 sheet), the Examiner has considered the references cited by Applicant.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsdorf et al. (U.S. Patent No. 5,432,200, cited by Applicant) in view of Remington's Pharmaceutical Sciences, ("Remington", cited by the Examiner).

Walsdorf et al. (US 5,432,200) teach a salt of potassium, magnesium and citrate having a potassium:magnesium:citrate ratio of "about" 4:1:2, (col. 3, lines 4-13 and 42). The process for preparing the salt includes mixing citric acid with water with uninterrupted agitation, and then adding a magnesium compound and potassium compound thereto to produce a dense, hydrated mixture (col. 3, lines 36-40). During the addition of the magnesium and potassium compound, the temperature conditions are controlled desirably below 100° C. It is further taught that the hydrated mixture preferably has a water content between about 10 weight percent and about 20 weight percent. Additional ions (see present claims 1, 5, 9 and 17) are provided for because Walsdorf et al. teach that the potassium and magnesium compounds include salts, such as those

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presently claimed, i.e., magnesium carbonate, magnesium oxide, magnesium hydroxide, potassium carbonate, potassium bicarbonate, (see present claims 14-15). Therefore, in an aqueous environment, such as that present in the preparation mixture, (col. 3, line 36, "water"), additional ions would necessarily be present. Dietary supplementation is also taught whereby the salt is administered to a host in need thereof (see the abstract at line 1).

The differences between the above and the claimed subject matter lies in that Walsdorf et al. fail to teach the specific stoichiometric ratios of potassium, magnesium and citrate as in present claims 1, 5, 9 and 17. Also, the particular water content present in the hydrated mixture, as well as the physical constants of the prepared salt are not disclosed, (see present claims 4, 8, 16 and 20). Finally, the patentees fail to highlight spray drying as the process used to dry their composition (see, for example, col. 3, line 2, "milled and *dried*", emphasis added).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Walsdorf et al. teach that the salt may have a potassium:magnesium:citrate ratio of "about" 4:1:2. Further, at col. 3, lines 11-13, the patentees admit that "[a]lthough the structure of the resultant product is not known with certainty, a *likely* structural formula for the preferred product is shown in Fig. 1." (emphasis added). Thus, the patentees provide for a variability of ratios not inconsistent with the ratios presently claimed. In the absence of evidence to the contrary, nothing unexpected is seen in varying the ratios of components in a manner specifically suggested by the reference. It appears that Applicant has done no more than take the invention of Walsdorf et al. to its next, logical step and perform tests to determine the actual structure of

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the product produced in the reference.

Also, the reference provides for a hydrated mixture. The determination that such level of hydration represents the claimed values is not seen to be an act of invention.

Further, the Examiner is not equipped to make a physical comparison between the presently claimed salt and that of the reference, (see MPEP § 2113, last sentence, "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Thus, because the product of Walsdorf et al. and that claimed appear to be the same or else not patentably distinct, it must be presumed that the physical constants presently claimed, e.g., the endothermic peak for decomposition, etc., would also have been within the scope of the teachings of the reference.

Finally, as noted above, Walsdorf et al. provide generally for a drying step in order to produce a powder suitable for processing into pharmaceutical compositions (Walsdorf et al. at col. 3, line 51 – col. 4, line 10). Therefore, one of ordinary skill in the art would have looked to conventional drying processes in order to practice the invention of the patentees. One such process that would have been known to the artisan would have been spray drying, which Remington teaches as being known for the processing of powders that are to be formed into pharmaceutical compositions (see pg. 1535, col. 1, under the heading "Spray Drying" and col. 1, first paragraph, i.e., "[p]owders are encountered in almost every aspect of pharmacy, both in industry and in practice. Drugs and other ingredients, when they occur in the solid state in the course of being processed into a dosage form, usually are in a more or less finely divided condition...").

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Accordingly, for the above reasons, it is believed that the presently claimed subject matter would have been obvious and therefore, claims 1-20 are properly rejected.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

March 3, 2006